UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,969	10/30/2003	Jason A. Demers	1062/D70	8503

73544 7590 12/10/2009

Michelle Saquet Temple
DEKA Research & Development Corp.
340 Commercial Street
Manchester, NH 03101-1129

EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,969	DEMERS ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-42,44-65 and 67-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-42,44-65, 67-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/09 has been entered.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Status of the claims

Claims 26-71 were previously pending. Claims 43 and 66 have been cancelled. Claims 26, 27, 28, 29, 30, 31, 33, 34, 36, 37, 40, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 56, 57, 59, 60, 61, 67, 68, 69, 70 and 71 have been amended. Claims 26-42, 44-65, 67-71 are currently pending. Claims 26-42, 44-65, 67-71 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 26, 35-36, 38, 41-42, 44, 49, 51, 57-59, 61-65, 69 are rejected under 35 USC 102 as being anticipated by Brenneman (US 5,466,220).

Brenneman discloses a drug vial mixing and transfer device having a piercing connector or a syringe attached to the end of one or more ports (port assembly) with interconnecting fluid passageways. Further the piercing connector is used to support and penetrate standard glass drug vials filled with powder or lyophilized drugs or liquid diluent, while the syringe is used to transfer liquid diluent and drug solutions between the vials and the syringe advantageously within a sealed system. Figure 1 is disclosed:

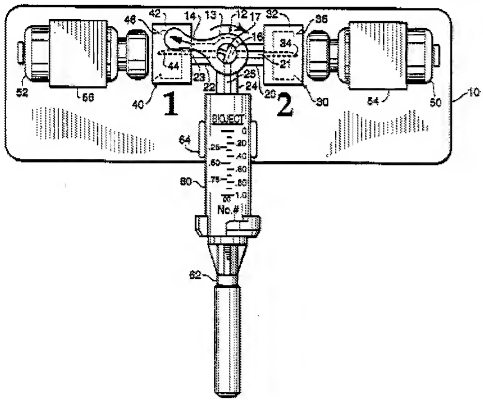

Figure 1 is a top view of the preferred embodiment of a novel drug vial mixing and transfer device. This figure shows the drug vial mixing and transfer device comprising a base 10, which is substantially flat and rectangular, with a stop cock type valve 12 mounted on the face of the base 10. The valve 12 comprises a valve body 12, a lever 13, a rotatable cylindrical stem 16, and three ports 20, 22 and 24 (i.e. a port assembly). The stem 16 is attached to the lever 14 and is axially located within the valve body 13. The three ports 20, 22, 24, with their corresponding fluid passageways 21, 23 and 25 extend outwardly from the valve body 13. A "T" shaped fluid pathway 17 is formed within the stem 16. The fluid pathway 17 communicates with the fluid passageways 21, 26 and 25, of the ports 20, 22, 24, controlling and directing the flow of the fluid within the device. The ports 20, 22, 24 are configured in a "T" shape arrangement, such that, for exemplary purposes only, the two opposing ports 20, 22, generally form the horizontal member of the "T" and the third port 24 generally forms the vertical member of the "T".

Connected to the end of the horizontal port 20, extending to the right of the valve 12 at position 2, is a piercing connector 30. The piercing connector 30 comprises a cylindrically cup shaped housing 32, a piercing cannula 34 (spike), and an internal annular claw 36. The cannula 34 is axially fixed within the housing 32, thus forming a fluid pathway, through the housing 32, that communicates with the fluid passageway 21 of the port 20. The claw 36 is located annularly around the inner edge of the connector's 30 opening to act as a vial retainer. An identical configuration exists on the end of the opposing horizontal port 22 at position "1" wherein a piercing connector 40 is connected

to the port 22. As above, the piercing connector 40 comprises a cylindrically cup shaped housing 2, a piercing cannula 44 and an annular claw 46. Also the cannula 44 is axially fixed within the housing 42, thus forming a fluid pathway, through the housing 42, that communicates with the fluid passageway 23 on the port 22.

Axially aligned with the piercing connector 30, at position "2" is a vial retainer 54. The retainer 54 slidably retains a powdered or lyophilized drug vial 50 in place, prior to operation, at a predetermined spacing form the connector 30. An identical vial retainer 56 is axially aligned with the opposing piercing connector 40, at position "1". The retainer 56 also slidably retains a liquid diluent or sterile water vial 52 in place, prior to operation, a predetermined spacing from the connector 40. The drug and liquid diluent vials 50, 52 can be of standard or non-standard construction.

A syringe 60 is connected to the end of the remaining vertical port 24 and communicates with the corresponding fluid passageway 25. The syringe 60 can be either a standard or non-standard syringe. A retainer 64 retains the syringe 60 in place on the face of the base 10. Preferably, the base 10 and the retainers 54, 56, 64 are formed of single piece molded plastic.

After slidably placing the drug a liquid diluent vials 50, 52 in their respective retainers 54, 56 and connecting the syringe 60 to the vertical port 24, the drug mixing and transfer device is packaged in a flexible protective packaging. This configuration creates a sealed sterile system (cols 1-3, and claims; see also Figures 3-4A and 4B). With respect to the limitation drawn to the coupling surfaces of the container receptacle and port assembly such limitation is deemed to be inherent to the system since as

taught by Brenneman the container receptacle and port assembly are adapted and configured to resist decoupling (e.g., col. 3). With regards to the limitations wherein the substance is a caustic substance and wherein the substance is an anti-pathogen compound, such limitations are not deemed to further limit the apparatus beyond the need to contain the substance in an appropriate vial such as a drug vial as taught by Brenneman (e.g., col. 7).

Therefore the reference is deemed to anticipate the claims above.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

US 5,464,123

Claims 26, 35-36, 38, 41-49, 51, 57-59, 61-65, 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Fowles et al. (US 6,610,040).

Fowles et al. disclose an apparatus for mixing a substance in a sealed container with a liquid, the substance being positioned in a container receptacle; the container receptacle capable of coupling with a port assembly to permit liquid to enter the container through the port assembly, the apparatus comprising: container spiking assembly for securing the container receptacle next to the port assembly; a container spiking assembly controller in communication with the container spiking assembly for

controlling coupling of the container receptacle with the port assembly and a liquid controller for controlling the flow of the liquid through the port assembly into the container to produce a combined substance and liquid; wherein the coupling surfaces of the container receptacle and port assembly are adapted and configured to resist decoupling (see, e.g., cols. 1-13 and claims).

Fowles et al. disclose an apparatus related generally to the delivery of a beneficial agent to a patient. More specifically, the present invention relates to an improved device for reconstituting a beneficial agent to be delivered to a patient. Many drugs are unstable even for a short period of time in a dissolved state and therefore are packaged, stored, and shipped in a powdered or lyophilized state to increase their shelf life. In order for powdered drugs to be given intravenously to a patient, the drugs must first be placed in liquid form. To this end, these drugs are mixed or reconstituted with a diluent before being delivered intravenously to a patient. The diluents may be, for example, a dextrose solution, a saline solution, or even water. Typically the drugs are stored in powdered form in glass vials or ampules. Other drugs, although in a liquid state, must still be diluted before administering to a patient. For example, some chemotherapy drugs are stored in glass vials or ampules, in a liquid state, but must be diluted prior to use. As used herein, reconstitution means to place the powdered drug in a drug already in liquid form, as well as, to further dilute a liquid drug.

Many companies that manufacture the drug do not make the diluent, and vice versa; therefore, the lyophilized drug and the diluent are sold separately. It is necessary for the doctor, pharmacist, nurse, or other medical personnel to mix the drug

with diluent prior to use. Reconstituting the drug presents a number of problems. The reconstitution procedure is time consuming and requires aseptic technique. Further, the proper drug and diluent must be utilized or the product must be disposed of.

The reconstitution procedure should be performed under sterile conditions. In some procedures for reconstituting, maintaining sterile conditions is difficult. Moreover, some drugs, such as chemotherapy drugs, are toxic and exposure to the medical personnel during the reconstitution procedure can be dangerous. Fowles et al. disclose a connector device for establishing fluid communication between a first container and a second container. The device has a first sleeve member having a first and a second end, the first sleeve member having at the first end a first attaching member adapted to attach to the first container. The device further has a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and movable with respect thereto from an inactivated position to an activated position, the second sleeve member having at the second end a second attaching member adapted to attach the second sleeve member to the second container. First and second piercing members project from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container, and the first and second piercing members are independently hermetically sealed. (See Figures 2-4).

FIG.5

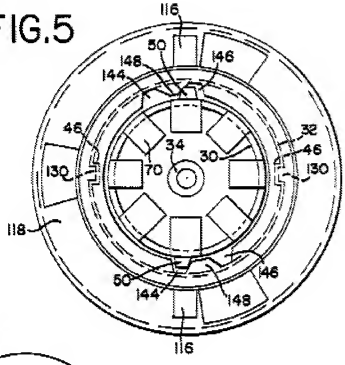

FIG.6

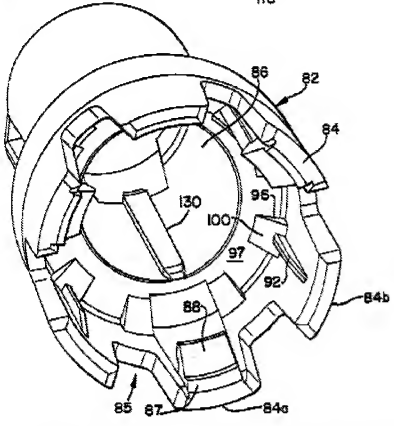

Figure 6 shows six circumferentially disposed and axially extending segmented

fingers for connecting to the vial 14. The segmented fingers 84 are generally trapezoidal in shape and separated by gaps 85 to define a vial receiving chamber 86 for receiving a top of the vial 14. The number of fingers may be more or fewer. Figure 9 shows that the second sleeve 32 has a sidewall with an outer 112 and an inner surface 113. A set of opposed gripping ribs 116 circumferentially spaced, extend along the outer wall. Sell also cols. 9-13.

Therefore the reference is deemed to anticipate the instant claims above, as drafted.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68, 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman (US 5,466,220) in view of Bloom et al. (6,070,761).

Brenneman is relied upon as above.

Brenneman does not expressly teach using sensors to determine the relative locations of the container and port assembly, contain a liquid controller, contain a pump chamber to measure the volume of the liquid,

Bloom et al. disclose a vial loading method and apparatus for intelligent admixture and delivery of intravenous drugs. The mechanism loads a vial (85) onto a cassette spike. It has a holder (207) movable between an unlocked position where the vial does not contact the spike, and a locked position in which it does contact the spike. A catch (247) locks the holder in the locked position.

Bloom et al. teach that when a holder is moved towards the locked position, an opposing force is provided by a spring. Several holders (207) are mounted on a panel (202). Each holder has an outer holding arm (208) and an inner arm (210), the latter pivotable to a position within the outer arm. If a large sized vial is used, the inner arm (210) is located in an upper, out-of-the-way position. If a small sized vial is used, the inner arm is pivoted to its lowered position within the outer arm. The two arms are sized to accommodate different sized vials. The catch includes a cam (254) with a flat lower surface (258). In the locked position, this retains the holder in its lowered position regardless of the restoring force of the spring. To remove the vial, a locking arm (248) of the catch is moved laterally until the flat lower surface of the cam no longer blocks the holder. The restoring force in the spring causes the holder to rise to its original position.

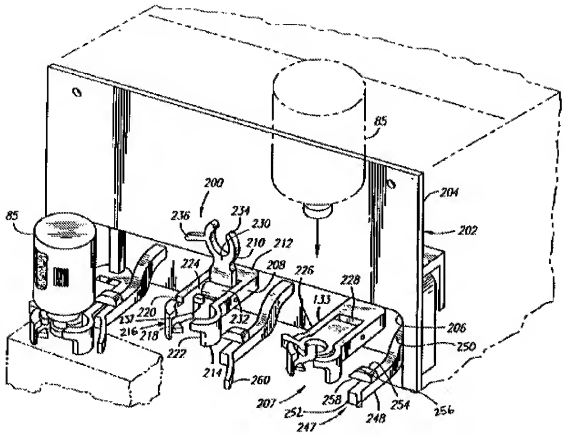

Fig. 12

Bloom et al. disclose an apparatus (Figures 12-13) for mixing a substance with a liquid comprising: a sealed container 85; port assembly 118; receiving chamber 202 with hinged cover 86 for receiving the container; controller 207 for controlling coupling of the container and the port assembly (col. 17, ll. 8-26); and liquid controller 88 comprising a cassette 77 and valves 112 (col. 16, ll.. 54-64). The liquid controller controls flow of liquid to and from the container (col. 15, ll. 47-58 and col. 16, ll. 54-64).

With regard to instant claims 37 and 60, Bloom et al. also teach a container sensing device at col. 19, ll. 53-54. The newly introduced limitation "without allowing decoupling of the container and the port assembly" is deemed to still read upon the Bloom patent, e.g., Figure 9, which teaches clamp 125 and Fig. 12, 216 and 218 (col. 17) which inhibit decoupling of the container and port assembly.

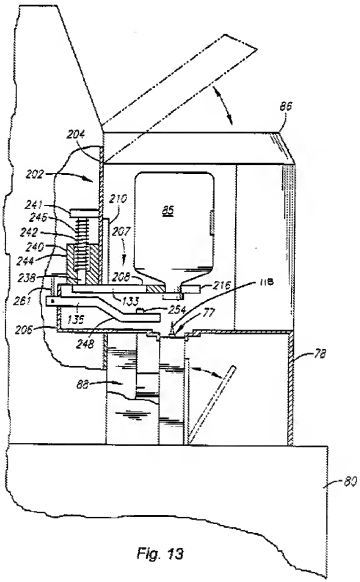

Fig. 13

Bloom et al. disclose in depth automatization of the apparatus above in cols. 12-37,, including having sensors, hinged doors, inner doors, entry devices, diaphragms (e.g., pneumatic pumps), control wheels, etc. and the necessary electronics in order to achieve automatization in a health care environment given the need for better and more reliable and consistent patient care, e.g., in hospitals where patients need reconstituted drugs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the device of Brenneman with automation technology as taught by Bloom et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so because automatization was desirable in order to mix drugs in a health care setting in order to reconstitute drugs in situ as needed, e.g., in a hospital, to accurately measure the amounts reconstituted and to provide better care to the patients as taught by Bloom et al (e.g., cols. 12-37). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because both Bloom et al. and Brenneman disclose apparatus for mixing drugs with liquids and contain similar elements such as vials, spikes, port assemblies, receptacle containers and so forth.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68, 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowles et al. (US 6,610,040) in view of Bloom et al. (6,070,761).

Fowles et al. and Bloom et al. are relied upon as above.

Fowles et al. disclose an apparatus related generally to the delivery of a beneficial agent to a patient. More specifically, the present invention relates to an improved device for reconstituting a beneficial agent to be delivered to a patient. Many drugs are unstable even for a short period of time in a dissolved state and therefore are packaged, stored, and shipped in a powdered or lyophilized state to increase their shelf life. In order for powdered drugs to be given intravenously to a patient, the drugs must first be placed in liquid form. To this end, these drugs are mixed or reconstituted with a diluent before being delivered intravenously to a patient. The diluents may be, for example, a dextrose solution, a saline solution, or even water. Typically the drugs are stored in powdered form in glass vials or ampules. Other drugs, although in a liquid state, must still be diluted before administering to a patient. For example, some chemotherapy drugs are stored in glass vials or ampules, in a liquid state, but must be diluted prior to use. As used herein, reconstitution means to place the powdered drug in a drug already in liquid form, as well as, to further dilute a liquid drug.

Many companies that manufacture the drug do not make the diluent, and vice versa; therefore, the lyophilized drug and the diluent are sold separately. It is necessary for the doctor, pharmacist, nurse, or other medical personnel to mix the drug with diluent prior to use. Reconstituting the drug presents a number of problems. The

reconstitution procedure is time consuming and requires aseptic technique. Further, the proper drug and diluent must be utilized or the product must be disposed of.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the device of Fowles et al. for reconstituting drugs with automation technology as taught by Bloom et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so because automatization was desirable in order to mix drugs in a health care setting in order to reconstitute drugs in situ as needed, e.g., in a hospital, to accurately measure the amounts reconstituted and to provide better care to the patients as taught by Bloom et al (e.g., cols. 12-37). One of ordinary skill in the art at the time the invention was made would have been motivated to do so because both Bloom et al. and Fowles et al. disclose apparatus for mixing drugs with liquids and contain similar elements such as vials, spikes, port assemblies, receptacle containers and so forth.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 12/09